

## **REMARKS**

### **Claim amendments**

Applicants have cancelled the claims that were not elected in response to the restriction requirement. The claims are cancelled without prejudice to filing one or more divisional applications.

### **Drawing objection**

The Examiner objected to the drawings submitted on filing under 37 C.F.R. § 1.83(a). Applicants have submitted a new set of formal drawings. The drawings make no substantive change to the drawing figures other than rendering the original informal drawings in formal fashion.

The drawings as filed (and the replacement drawings) show every feature of the claims, as will be explained below. The “single longitudinal axis” referenced in claims 2, 8 and 12 refers to the path of travel of the carrier as it is moved between a loading station in which the carrier is received and a sealing station and incubation loading station further down the path of travel. This axis is defined by the guide 108 of the transport system 1000, shown in Figures 19, 29, 30, 32 as explained at page 39 lines 8 et seq. While the axis per se is not specifically called out as such in the drawings, a person skilled in the art would recognize it as being the direction of movement of the carrier that is accomplished by the transport system 1000, i.e., the axis defined by the guide 108 which guides the carrier along the longitudinal path shown in the above figures. Approval of the drawings and withdrawal of the objection is requested.

### **Specification amendment and objection**

The specification at page 39 has been amended to correct the typo error in the number of the transport system. The transport system is described and shown in the drawings as item 1000, not item 100.

The specification was objected to for alleged failure to describe a “separate sensor station” recited in claim 24. Claim 24 recites “a sensor station for determining the presence of the carrier and the presence and location of the test sample devices in the carrier.” The sensor station is shown in Figure 17 as the reflective sensor 1040 which detects the carrier and a reflective sensor 1042 (also shown in Figure 17) which both counts and determines the location in the carrier of the test sample devices. The two sensors 1040 and 1042 constitute the recited sensor station. See page 40 lines 6-16, page 44, lines 10-23. Accordingly, the objection to the specification should be withdrawn.

### **§ 112 rejections**

Claims 1-13 and 18-24 were rejected under 35 U.S.C. § 112 ¶ 2 for failure to particularly point out and distinctly claim the rejection.

Claim 1 was rejected for reciting “adapted for manual insertion” of the sample carrier, the Examiner stating that it is unclear as to what structural features of the vacuum station allow the manual insertion. The meaning of the term “adapted for manual insertion” is straightforward and not in any way unclear or indefinite. The phrase means “made fit for<sup>1</sup> manual insertion.” In the illustrated embodiment, the structural features which permit such manual insertion are shown in Figure 1 as the door 302 and the structures defining the opening of the vacuum

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<sup>1</sup> “Adapt” means “to make fit (as for a specific or new use or situation) often by modification. Webster’s 9<sup>th</sup> new collegiate dictionary, p. 55 (1991).

chamber 304 in Figure 3A which allow the user to simply place (by hand) the carrier inside the vacuum chamber 304. See page 22 lines 1-4. The term “manual” is used in the ordinary sense of “by hand”<sup>2</sup>. “Manual insertion” means inserted by hand. The language of the claim is sufficiently clear. The Examiner is raising alleged ambiguity where there is none. The rejection should be withdrawn.

Similar remarks hold for claims 10-11. As to the feature of claim 11 of “a carrier loading and unloading station remote from said vacuum station *adapted for manual insertion* of said carrier into said carrier and test device processing subsystem . . .”, the highlighted phrase means the same thing as it does for claims 1 and 10 – made fit for manual insertion. The structures in the illustrated embodiment that facilitate manual insertion of the carrier into the carrier and test device processing system are the door 14 and the opening of the loading station 16 shown in Figure 3A that permits the user to simply manually place the carrier inside the opening into the carrier and test device processing subsystem contained therein. See page 23 lines 2-18.

Claim 1 was further rejected for alleged lack of clarity as to whether a controlling device was involved in a control of vacuum to load the test sample into the test sample devices. Claim 1 has been amended to add a vacuum controller to the claim. For support, see specification at page 22 lines 10-14 (“the rate of change of the vacuum is monitored and regulated by pneumatic servo feedback system under microprocessor control”).

The Examiner further objects to the term in claims 5, 10 and 11 which state that the processing system is “remote” from the vacuum station. The applicants use this term to mean simply that the processing system and vacuum station are separate from each other, in two

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<sup>2</sup> “Manual” is used in the ordinary dictionary sense: “of, relating to, or involving the hands”. Webster’s 9<sup>th</sup> new collegiate dictionary, p. 725 (1991).

distinct locations, as shown in Figures 1, 3A, 4, 5 and the other figures. Although the term “remote” is a relative term, the term “remote” is bounded because claim 1 itself recites that “wherein said carrier and test device processing subsystem and said vacuum station are integrated into a single instrument.” Thus, when the entire claim is read, and when the word “remote” is viewed in the context of the specification and drawings, it is clear that the vacuum station and carrier and test device processing subsystem are a) both integrated into a single instrument, but b) in separate and distinct locations. Therefore, the applicants submit that the term “remote” does not cause the claim to be indefinite. The applicants also note that inclusion of a relative term in a claim does not automatically render a claim indefinite. See MPEP § 2173.05(b). The test is whether a person skilled in the art would understand what is claimed. As explained above, one would understand the term “remote” as it is being used in the instant application.

Claim 9 was rejected as allegedly indefinite for reciting both the panels and the user interface. The claim has been amended to recite that the user interface provides operator controls for the instrument. Therefore, the front panels are clearly distinguished from the user interface providing operator controls.

Claims 18 and 20 were rejected as being allegedly unclear as to what structural features of a cover panel would provide access for a thermometer. The claims recite “. . . an incubation station having a cover panel, said cover panel providing access for a thermometer measuring the temperature of said incubation station, . . .” Applicants do not wish to be constrained to any particular design of a structural feature for physically holding the thermometer, and hence while

a particular structure is shown in Figures 37 and 38 and described at page 33 line 17 et seq., applicants do not consider their invention to be so limited. The question under 35 U.S.C. § 112 is whether a person skilled in the art would understand what the claim means. The claim simply recites that the incubation station has a cover panel which provides access for a thermometer which measures the temperature of the incubation station. No further recitation of structure is believed needed since a person skilled in the art would understand that the claim means just what it says it does.

#### **Information disclosure statement**

Applicants wish to bring to the Examiner's attention U.S. Patents 6,156,565 and Design patent D 377455. The '565 patent describes the incubation station of the subject Fanning '006 patent. The Design patent shows the ornamental design of the Fanning '006 instrument and the cover panels, user interface, access door to load the cassette and boat into the instrument, and a door for accessing to the disposal station (Fanning '006, Figure 2, station 900) containing test sample cards after processing. A PTO -1449 form for the Examiner's initialization is filed herewith. Please charge any required fees for consideration of the references to Deposit Account no. 13-2490.

#### **§ 103 Rejection**

The Examiner has rejected claims 1-13 and 18-24 as obvious over Fanning, US 5,869,006.

With respect to claims 1-10, 13 and 22, the Examiner states that that the prior Fanning patent describes the various stations, and while it does not teach that the boat 22 (carrier) is manually loaded into the vacuum station, non-automatic sample loading into vacuum chambers is well known in the art. The Examiner contends that the ordinary skilled artisan would have employed a number of non automatic operations (including loading of a vacuum station) in the modified automatic apparatus of Fanning in order to gain more flexibility for user input and to simplify controlling sub-systems, which would also reduce overall cost.

Applicants have amended claim 1 to recite a further difference from the prior Fanning system, in that it now recites that the carrier and test device processing subsystem includes an optically-controlled transport system for translating the carrier within the carrier and test device processing subsystem. The Fanning system relies on independent motor-driven paddle arrangements to drag the boat around the base pan. The system includes firmware which counts steps in the stepper motor as a way of knowing how much the motor has rotated and thus how much the paddle has carrier has moved. Nothing in Fanning suggests is in any way that this system is unsatisfactory. There is nothing in Fanning suggests an optically controlled system for moving the boat is desirable.

As to the separate (remote) manual vacuum loading station and carrier processing systems, the present inventive arrangement is not hinted or suggested at in Fanning and there is nothing in Fanning to suggest that the fully automatic instrument could or should be redesigned in the manner claimed. Conceptually, Fanning and the invention of claim 1 are quite different. Fanning represents an instrument that is totally automated after the cassette with sample cards are loaded within the instrument. No manual operations are involved in any processing steps or in movement of the carrier or test devices into any station for processing.

While the present invention was motivated by an interest in designing a smaller and lower cost alternative to a totally automated system as in Fanning, see page 15 lines 3 et seq., the desirability of such a system is not contemplated in Fanning. The Examiner is apparently using hindsight and the applicants own disclosure to bootstrap the obviousness argument, rather than relying on the teachings of the art and not using the benefit of the instant disclosure in order to determine what would have been obvious given the disclosure of Fanning. Given Fanning alone (and not having the benefit of the applicants' disclosure), it is certainly not obvious how one would redesign the system of Fanning to achieve a smaller and lower cost version of the instrument, other than to go back to the original design of the prior Charles et al. patent 4,188,280 cited at Fanning at col. 1 lines 61-63. Nor is it obvious at all that to achieve a more compact and lower cost instrument one would arrive at the solution which is characterized in being a single instrument which incorporates both vacuum loading and test sample processing but 1) features manual loading of the carrier and removal of the carrier from a vacuum station (not contemplated or obvious from Fanning), 2) a separate carrier and test sample processing subsystem which features manual insertion of the carrier and test devices into the subsystem after vacuum loading (not contemplated in Fanning), or 3) an optically controlled transport system in the carrier and test sample processing system (not contemplated or obvious over Fanning).

As to claims 2 and 8, the Examiner has not established a basis for rejection of these claims. Claims 2 and 8 recite that the transport system moves the carrier along a single longitudinal axis to all the modules. This is different from Fanning. In Fanning, the system moves the boat and cassette ("carrier") along three axes: a first axis from right to left for pipetting and diluting operations, a second axis along the left hand edge of the base pan for

vacuum loading, and a third axis from left to right for card sealing and loading of the cards into the carousel incubation station.

As to claim 9, the claim recites “a first door providing access for loading said carrier into said vacuum station; a second door providing access for loading said carrier into said carrier and test device processing subsystem; and a third door providing access to a disposal system receiving said test devices after completion of processing of said test devices by said modules.”

While Fanning does show cover panels on the instrument, it does not have a separate door for providing access for loading the carrier into the vacuum station. Fanning’s system provides a single access point for loading the boat and cassette combination into the instrument at the lower right hand side of the instrument when the user is facing the instrument (Figure 7, lower right and corner position). The vacuum loading is performed automatically within the instrument and no separate access point or door is provided for the manual loading of the carrier into the vacuum loading station. Nothing in Fanning suggests the modification of the instrument as recited in claim 9.

As to claim 10, this claim recites:

10. (original) An integrated system for processing a plurality of test samples and test sample devices for receiving said test samples, said test samples received in individual fluid receptacles, said system for use with a carrier holding a plurality of said fluid receptacles and a plurality of said test sample devices in a spaced relationship, each of said test sample devices having a transfer tube providing fluid communication between said test sample device and one of said fluid receptacles received in said carrier, the system comprising:

a vacuum station adapted for manual insertion of said carrier into said vacuum station and removal of said carrier from said vacuum station, said vacuum station further comprising a source of vacuum, said vacuum source controlled so as to load said test samples from said individual fluid receptacles into respective test sample devices;

a first door providing access to said vacuum station;

a carrier and test device processing subsystem remote from said vacuum station, said carrier and test device processing system comprising apparatus for sealing said test devices, incubating said test devices, and reading said test devices; and

a second door providing access for said carrier to said carrier and test device processing subsystem.

Claim 10 recites a completely different configuration for a sample testing machine from the arrangement of Fanning. Fanning provides a single access point (door) for insertion of the cassette and test sample cards into the instrument and all further processing is performed automatically. Fanning does not describe or suggest a separate a vacuum station adapted for manual insertion of a carrier into said vacuum station and removal of the carrier from the vacuum station, and a door for such a station. While the present invention was motivated by an interest in designing a smaller and lower cost alternative to a totally automated system as in Fanning, see page 15 lines 3 et seq., the desirability of such a system is not contemplated in Fanning. The Examiner is apparently using hindsight and the applicants own disclosure to bootstrap the obviousness argument, rather than relying on the teachings of Fanning and not using the benefit of the instant disclosure in order to determine what would have been obvious given the disclosure of Fanning.

Furthermore, the prior system based on the Charles et al. patent 4,188,280 cited at Fanning at col. 1 lines 61-63 included a separate “filler/sealer” module which performed both the vacuum filling of the test cards and the sealing of the cards. In contrast, claim 10 recites that the vacuum loading of the test cards occurs in the vacuum station but the sealing of the test cards occurs in the carrier and test device processing subsystem. This arrangement of elements is not at all contemplated or obvious from either the Fanning patent or the prior Charles et al. patent.

As to claim 18 and 20, these claims recite "an incubation station having a cover panel, said cover panel providing access for a thermometer measuring the temperature of said incubation station". The Examiner merely cites to the "user friendly and attractive panel" of the Fanning instrument. The Examiner has not cited any teaching in Fanning of a cover panel providing access for a thermometer, nor is any teaching contained in Fanning. While the thermometer is not positively recited in the claim, what is positively recited is a cover panel which provides access to a thermometer. Fanning's teaching of a cover panel does not amount to a teaching of a cover panel which provides access to a thermometer.

Claim 24 further recites a sensor station for determining the presence of the carrier and the presence and location of the test sample devices in the carrier. The Examiner has not addressed this claim. Fanning does not include or suggest such as sensor station.

#### Conclusion

Applicant submits that the rejections should all be withdrawn and the case passed to issuance. Prompt and favorable action to that end is requested.

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The undersigned hereby certifies that the foregoing Amendment is being deposited as first class mail, postage prepaid, in an envelope addressed to Mail Stop Amendment Commissioner for Patents, PO Box 1450 Alexandria VA 22313-1450 on this 20 th day of December, 2007.

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